

In re National Prescription Opiate Litigation: MDL 2804

Summary Sheet of Concise Issues Raised

Opposition Name: Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude "Gateway" Opinions of Drs. Lembke, Gruber and Keyes

Opposing Parties: Plaintiffs Summit County and Cuyahoga County

Issue #1. Are the opinions of Drs. Lembke and Keyes, that prescription opioids are a gateway to misuse of, and addiction to, both prescription opioids and illicit drugs admissible under *Daubert* and Fed. R. Evid. 702?

Answer: Yes. Defendants argue that there is no scientific evidence of a causal link between "properly prescribed pain patients" and illicit drug use, and characterize this effect as a "hypothesis" without support. These arguments are based on a misleading and selective review of the scientific literature and Plaintiffs' expert reports, omitting sources that contradict the defense position. In fact, the Gateway Effect has been widely accepted in the scientific literature, and the progression from medical use to non-medical use to illicit drug use has also been well-documented. Drs. Lembke and Keyes relied on a substantial body of scientific evidence in reaching their conclusions, including an authoritative report of the National Academy of Science, Engineering and Medicine and numerous peer-reviewed scientific studies. The review of scientific literature is a sound methodology. *In re Gadolinium-Based Contrast Agents Products Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, *mod. on recon.*, 2010 WL 5173568, *aff'd sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014) (finding expert testimony based on review of scientific literature admissible); *see also, In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712738 (N.D. Ohio 2011) ("Courts have admitted expert testimony as reliable where experts extrapolate their opinions from their knowledge and experience combined with a review of the relevant scientific literature.") Plaintiffs' experts followed reliable methodologies to offer admissible opinions that both medical and non-medical exposure to Defendants' prescription opioids caused increased use of heroin and fentanyl. Dr. Lembke's and Dr. Keyes' pre-litigation publications of their findings, which match their opinions in this case, provide further assurance of the reliability of their opinions. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434 (6th Cir. 2007) ("That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science").

Issue #2: Are the opinions of Dr. Gruber, that shipments of prescription opioids caused illicit-opioid related harms, admissible under *Daubert* and Fed. R. Evid. 702?

Answer: Yes. Professor Gruber, a renowned MIT professor, applied well-recognized methods in his field of health economics, including analyses showing a close and causal relationship between the extent of shipments of prescription opioids to geographic areas and the extent of illicit opioid-related harms, including mortality. Professor Gruber's methodology included regression analyses to consider and rule out alternative causes for the higher mortality observed in areas with higher shipments of prescription opioids. Defendants' arguments are based on selective deposition excerpts that ignore Professor Gruber's actual opinions. Plaintiffs respectfully direct the Court's attention to their Opposition to Defendants' *Daubert* Motion to Exclude the Opinions Offered by Jonathan Gruber, for further exposition of the reliability of his methods and admissibility of his opinions.